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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,981	12/18/2001	Hao Yuan	13774-002001	2606
75	590 08/08/2002	;	•	
Fish & Richardson 225 Franklin Street Boston, MA 02110-2804		% *	EXAMINER OH, SIMON J	
		:		
;		(ART UNIT	PAPER NUMBER
:			1615	
		•	DATE MAILED: 08/08/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/018,981	YUAN, HAO			
		Examiner	Art Unit			
		Simon J. Oh	1615			
The MAILING DATE of this communication appears on the cover sheet with the correspondenc address Period for Reply						
A SH THE I - Exter after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply ly within the statutory minimum of thirty (30 rill apply and will expire SIX (6) MONTHS cause the application to become ABAND	be timely filed) days will be considered timely. from the mailing date of this communication. ONED (35 U.S.C. § 133).			
Status						
1)	Responsive to communication(s) filed on					
2a) <u></u>	<i>,</i> —	s action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
· ·	Claim(s) <u>1-15</u> is/are pending in the application					
-	4a) Of the above claim(s) is/are withdrawn from consideration.					
·	☑ Claim(s) <u>1-15</u> is/are rejected.					
	Claim(s) is/are objected to.					
	8) Claim(s) are subject to restriction and/or election requirement.					
Applicati	on Papers					
9) The specification is objected to by the Examiner.						
10) 🔲 🤈	10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) 🔲 🧻	The proposed drawing correction filed on		oproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.						
12) ☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a)[☑ All b)☑ Some * c)☐ None of:					
	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
* S	 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
) The translation of the foreign language proacknowledgment is made of a claim for domesti	· ·				
Attachmen		,	· · · · · · · · · · · · · · · · · · ·			
2) 🔲 Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Inform	mary (PTO-413) Paper No(s) mal Patent Application (PTO-152)			

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on June 18, 1999. It is noted, however, that applicant has not filed a certified copy of the 99109147.7 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "[a] kind of extract" renders the claim indefinite because it is unclear because the claim includes elements not actually disclosed (those encompassed by "[a] kind of extract"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 3-5, 7, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by the Liu *et al.* article.

The Liu et al. article discloses the existence of the Shengmai Chenggu tablet, which consists of the leaves of Cajanus cajan (L.) Millsp; the tablet is disclosed to be effective for treating necrosis of the femoral head. The leaves of Cajanus cajan (L.) Millsp are disclosed as being effective in treating injury, burn infection, sores, and jaundice; the leaves are also reported to possess anti-septic and anti-inflammation properties (See Page 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Liu *et al*. article in view of the Yuan document (Chinese Patent Document No. CN 1174052).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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The Liu *et al.* article discloses the existence of the *Shengmai Chenggu* tablet, which consists of the leaves of *Cajanus cajan (L.)* Millsp; the tablet is disclosed to be effective for treating necrosis of the femoral head. The leaves of *Cajanus cajan (L.)* Millsp are disclosed as being effective in treating injury, burn infection, sores, and jaundice; the leaves are also reported to possess anti-septic and anti-inflammation properties (See Page 7). In addition, a process for preparing an extract and a powder from the leaves of *Cajanus cajan (L.)* Millsp is disclosed. The process involves taking a batch of the leaves and cutting into pieces. Water is added in amount that is 10 times that of the leaves. The mixture is heated and boiled 3 times for a duration of 1 hour each time. The filtered solution is concentrated in a vacuum, and the remaining paste is dried and then pulverized into powder (See Page 8, Section 2.1.1). This process is then optimized so that the mixture of leaves and water is boiled 3 times for a duration of 1.5 hours each time (See Page 7, Abstract; and Page 9, Section 4).

The Liu *et al.* article does not disclose any specific settings for process variables. The article also does not disclose a method of treatment comprising the administration of leaves of *Cajanus cajan (L.)* Millsp or an extract thereof for ameliorating of hemorheological index, reinforcing immunological functions, treating angina of coronary heart disease, treating fracture, treating cerebral infarction, treating the infected surface of the wound of an open fracture, or treating osteoporosis.

The Yuan document discloses the use of the leaves of *Cajanus cajan (L.)* Millsp in a medical preparation for curing ischemic necrosis of the femoral head. This medical preparation is reported to prevent microcirculation, promoting blood vessel regeneration, absorbing necrotic bone, and regenerating new bone (See Abstract).

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It would be obvious to one of ordinary skill in the art to combine the teachings of Liu et al. and Yuan into the objects of the present invention. The Liu et al. article teaches the basic method of preparing an extract of the leaves of Cajanus cajan (L.) Millsp, as well as the therapeutic properties of such a preparation. The Yuan document also teaches a medical preparation of Cajanus cajan (L.) Millsp, as well as disclosing additional therapeutic properties of such a composition. One of ordinary skill in the art to combine the references because as stated in In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Regarding claim limitations drawn to specific settings for process variables, it is the position of the examiner what where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Regarding claim limitations drawn to treatments for specific diseases or conditions, it is the position of the examiner that the general therapeutic properties taught by the prior art obviates these claim limitations. The prior art establishes certain generic features of preparations of Cajanus cajan (L.) Millsp, including the absorption of necrotic tissue, promotion of bone health, promotion of blood vessel health, antiseptic properties, wound and sore healing properties, and anti-inflammatory properties. The discovery of treatments for specific conditions laid out by the applicant would be obvious for one of ordinary skill in the art through routine experimentation, in light of the general therapeutic properties of Cajanus cajan

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(L.) Millsp disclosed by the prior art. Thus, the claimed invention as a whole is prima facie

obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The

examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3014 for regular

communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh Patent Examiner

AU 1615

sjo

August 1, 2002

THURMANIK, PAGE
SUPERVISORY PATENT EXAMINER
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